

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

KIMBERLY C. CUTONE and
ANTHONY CUTONE,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

CIVIL ACTION No. 04-CV-12725 (JLT)

**DEFENDANT ELI LILLY AND COMPANY'S
CONSENT MOTION FOR LEAVE TO FILE REPLY BRIEF**

Defendant Eli Lilly and Company ("Lilly") moves this court for leave to file a Reply in support of its Motion to Strike Statement of Harold Sparr. Lilly's Reply is filed concurrently herewith.

As grounds for this motion, Lilly states that the Reply is necessary to address arguments raised in Plaintiff's Opposition and additional statements submitted by Plaintiffs with their opposition that were not previously part of the record. Lilly believes the Reply will be of assistance to the Court in resolving the issues raised by Lilly's Motion to Strike.

WHEREFORE, Lilly requests the Court grant this motion for leave to file the Reply brief filed concurrently herewith.

Respectfully submitted,

ELI LILLY AND COMPANY
by its attorneys

/s/ James J. Dillon
James J. Dillon (BBO# 124660)
Brian L. Henninger (BBO# 657926)
Foley Hoag LLP
155 Seaport Boulevard
Boston, MA 02210-2600
(617) 832-1000

Dated: September 5, 2006

LOCAL RULE 7.1(A)(2) CONFERRAL CERTIFICATION

I, Ericka Harper Snyder certify that on August 22, 2006, I conferred with Plaintiffs' counsel regarding Lilly's Motion for Leave to File a Reply Brief. Plaintiffs' counsel consented to the Motion.

/s/ Ericka Harper Snyder

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

KIMBERLY C. CUTONE and
ANTHONY CUTONE,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

CIVIL ACTION No. 04-CV-12725 (JLT)

**ELI LILLY AND COMPANY’S REPLY BRIEF IN SUPPORT OF ITS
MOTION TO STRIKE STATEMENT OF HAROLD SPARR**

In her Opposition to Defendant Eli Lilly’s Motion to Strike the Statement of Harold Sparr (“Plaintiff’s Opposition”), Plaintiff argues that Mr. Sparr’s “expert” testimony should not be excluded on summary judgment. In this case, however, Plaintiff relies on Mr. Sparr’s statement notwithstanding deposition testimony which disclosed that he had no basis for the sweeping statements made and that he is employed as a consultant for Plaintiff’s counsel. Mr. Sparr’s supposed expert testimony is based on (1) his personal experience as a retail pharmacist in four pharmacies in Belmont and Boston and in professional associations, (2) a survey study commissioned by Plaintiff’s counsel, and (3) interviews with pharmacists at the direction of Plaintiff’s counsel. Yet Mr. Sparr never worked at the pharmacy where Plaintiff’s mother allegedly obtained DES (Bayard Pharmacy), nor did he work in any other pharmacies in Allston, Massachusetts. His “market survey” suffers from many flaws, not the least of which was Mr. Sparr’s inappropriate selection criteria and his failure to verify the accuracy of any responses. His interviews with pharmacists were directed by Plaintiff’s counsel for the stated goal of determining whether the pharmacist recalled dispensing Lilly’s DES. For these reasons, Mr.

Sparr's "expert" testimony does not rise the level of reliability and relevance required by F.R.E. 702 and Daubert, and must be excluded.

A. PLAINTIFF'S AUTHORITIES RECOGNIZE THAT "EXPERT" TESTIMONY CAN BE EXCLUDED ON SUMMARY JUDGMENT

Plaintiff argues in her Opposition that the Court cannot exclude "expert" testimony on summary judgment without a Fed. R. Evid. 104(a) hearing unless the defects are obvious on the face of the proffer. *See* Plaintiff's Opposition, at 2-7. Indeed, the authorities cited by Plaintiff in support of its Rule 104(a) hearing make room for exclusion of expert testimony that is defective on its face, *Cortez-Irizarry v. Corporacion Insular*, 111 F.3d 184, 188 (1st Cir. 1997), or that is irresponsible and irrelevant, *Tuf Racing Prods., Inc. v. American Suzuki Motor Corp.*, 223 F.3d 585, 591 (7th Cir. 2000). Lilly's Motion to Strike is premised on the argument that Mr. Sparr's "expertise" is facially defective because it is based on a limited personal experience not relevant to the issue in this case and a market survey that shed no light on the stocking and dispensing practices of a particular Allston, Massachusetts pharmacy in 1969 and 1970. Mr. Sparr's "expert" testimony on the Massachusetts DES market is mere speculation and has no relevance to this case. *See, e.g., Hernandez v. NATMAR, Inc.* 1998 WL 37497 at *9-10 slip op. (D.D.C. Jan. 22, 1998) (disregarding Plaintiff's expert report on summary judgment because it was based on pure speculation).

B. MR. SPARR'S PERSONAL EXPERIENCE AS A MASSACHUSETTS PHARMACIST IS IRRELEVANT

Mr. Sparr never worked at the pharmacy where Plaintiff's mother allegedly obtained DES, nor did he work in any pharmacies located in Allston, Massachusetts. Indeed, Mr. Sparr has practiced in only four Massachusetts pharmacies. Statement of Harold Sparr, R.Ph., dated May 16, 2006 (Levine Aff., Ex. 1). Having no experience with any pharmacies in Allston, Mr.

Sparr's testimony with respect to the dispensing practices at Bayard Pharmacy is pure speculation.

C. MR. SPARR'S PERSONAL EXPERIENCE AS A MEMBER OF THE MASSACHUSETTS PHARMACY COMMUNITY IS IRRELEVANT

Recognizing that Mr. Sparr has no personal knowledge of the DES dispensed at Bayard Pharmacy or even in Allston, Massachusetts, Plaintiff cites his other experience in the Massachusetts pharmacy community as a basis for his "expertise." *See* Plaintiff's Opposition at 6, 14-15. A brief look at some of these activities reveals that they impart no expertise to Mr. Sparr that is relevant to this case.

- President, Massachusetts Board of Registration of Pharmacy -- Mr. Sparr was not appointed or elected to this position until 1995.
- President, Massachusetts College of Pharmacy and Health Services Alumni Association -- Mr. Sparr was not appointed or elected to this position until 1998.
- Reviewing and Personally Observing Massachusetts Retail Drug Store Practices And The DES Environment, 1954-1971 -- Mr. Sparr admitted at his deposition that the only retail drug store practices he observed were those of the stores in which he worked. *See* Sparr Tr. at 116-17 (Dwyer Aff., Exh. 1).
- Visited Hundreds of Boston-Area Pharmacies; Talked to Hundreds of Pharmacists -- Mr. Sparr conducted these interviews and visits sometime after 2003 while he was working for Plaintiff's counsel. Mr. Sparr understood that the goal of the interview was to confirm that the pharmacist remembered dispensing Lilly. *See id.* at 15-19, 55-57, 84-90 (Dwyer Aff., Exh. 1). Indeed, Mr. Sparr told pharmacists that he wanted to speak with them in connection with "current lawsuits [involving] the Liability Insurance Company who insured Eli Lilly & Co." *See* Letter from Harold Sparr to George Friedman, R.Ph., dated December 5, 2003 (Dwyer Aff., Exh. 6). Mr. Sparr made no effort to check the memories of the pharmacists with which he spoke or to organized notes of his conversations. *See* Sparr Tr. at 15-19, 55-57, 84-90 (Dwyer Aff., Exh. 1). *See also* Reference Manual on Scientific Evidence (2d ed. 2000), at 253 ("[I]nterviewers should record verbatim both what the respondent says and what the interviewer says in the attempt to get clarification. Failure to record every party of the exchange in the order in which it occurs raises

questions about the reliability of the survey, because neither the court nor the opposing party can evaluate whether the probe affected the views expressed by the respondent.”).

- Teacher, Massachusetts College of Pharmacy and Northeastern University -- Mr. Sparr’s role teaching and supervising students in hospital pharmacies after 1970 did not involve seeing or filling any prescriptions for DES for the use in pregnancy. *See id.* at 118-19 (Dwyer Aff., Exh. 1).

There is no reason to believe that Mr. Sparr learned anything relevant to the specific facts of *this case* from the activities above. For all these reasons, Mr. Sparr’s membership in the Massachusetts pharmacy community does not qualify him as an expert on DES market in Massachusetts in 1969-70.

D. MR. SPARR’S SURVEY METHODS ARE NOT RELIABLE AND HAVE NO RELEVANCE TO THE FACTS OF THIS CASE.

In order for a witness to offer an expert opinion, he must be “qualified as an expert by knowledge, skill, experience, training, or education” and his testimony must: 1) be based upon sufficient facts or data; 2) be the product of reliable principles and methods; and 3) apply the principles and methods reliably to the facts of the case. F.R.E. 702. While Plaintiff’s proffer fails in all of these areas¹, Defendant wishes to focus the Court’s attention on several facts which underscore the necessary conclusion that Mr. Sparr’s has not and cannot apply his survey methods reliably to this case.²

¹ Lilly’s Motion to Strike fully sets forth the facts and the law that support the conclusion that Mr. Sparr is not qualified by “knowledge, skill, experience, training, or education” to offer an expert opinion on the market share of Lilly’s DES in Massachusetts from 1955-1971. *See* Lilly’s Motion to Strike at 2-13. Lilly’s Motion to Strike also details the insufficiencies in the facts and data upon which Mr. Sparr bases his opinion and on the unreliability of Mr. Sparr’s principles and methods. *See* Lilly’s Motion to Strike at 2-13.

² Plaintiff cites cases for the proposition that whether an expert’s methodology is reliable “goes only to the weight, and not the admissibility, of the surveys.” Plaintiff’s Opposition at 13 (citing *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134 (9th Cir. 1997) and *E&J Gallo Winery v. Gallo Cattle Co.*, 967 F.2d 1280 (9th Cir. 1992)). However, this statement must be read in context. The court stated that “as long as [the surveys] are conducted according to accepted principles ... a jury should be able to determine whether asserted technical deficiencies undermine a survey’s probative value.” *Southland Sod* at 1143, n.8. Here, Plaintiff has utterly failed to demonstrate that Mr. Sparr’s survey was conducted according to accepted principles.

First, Plaintiff admits that Mr. Sparr's survey only addresses the market share where no brand was specified on the prescription. *See, e.g.*, Plaintiff's Opposition at 11 ("The study was not interested in those times in which the brand name was specified; of course the brand specified would have been dispensed in those circumstances, to do otherwise would have been contrary to the ethical practice of pharmacy."). Here, there is no evidence about Plaintiff's mother's prescription at all, much less whether it failed to specify a brand. Hence the "survey" does not address the issue of what DES was dispensed in this case. There also is no evidence as to what percentage of DES prescriptions were written without a brand specified. Thus, it is entirely possible that the prescription at issue specified a brand and that the brand was one other than Lilly. Mr. Sparr cannot conclude anything about the DES market at large based solely on a survey of prescribing practices where the brand was not specified.

Second, Mr. Sparr's "market survey" was limited to pharmacists (1) first licensed in Massachusetts from 1963 to 1967, and (2) still practicing in 2004. Not only does this selection serves no scientific purpose, it is unreliable for determining a proper sample of pharmacists. Only those pharmacists who had been practicing for less than six years in 1969 and who were still practicing in 2004 were allowed to complete the survey, thereby excluding pharmacists who had more experience (and presumably more responsibility) in their respective pharmacies, as well as pharmacists who have since retired or moved.

Third, Mr. Sparr's survey does not take into account the reliability of the pharmacists' memories of a drug dispensed more than 35 years ago. As one respondent aptly noted, "I believe that we only stocked Lilly's brand but I could be mistaken. That was a long time ago!" August 26, 2004 Letter from Hannelore Vanderschmidt to Harold Sparr (Levine Aff., Ex. 2). Yet when asked whether he attempted to verify the accuracy of any of the respondents' memories about the

DES dispensed in their stores, Mr. Sparr responded “No. How could I?” Sparr Tr. at 97 (Dwyer Aff., Exh. 1).

Fourth, the survey *did not ask* what brand of DES each pharmacy stocked, but rather asked what brand would have been “*primarily* dispensed.” Statement of Harold Sparr, Attachment 1 -- “Stilbestrol Survey for Pharmacists” (emphasis in original) (Dwyer Aff., Exh. 4). The respondents were not encouraged to list all brands of diethylstilbestrol available in their respective pharmacies, much less given clear instructions for what “*primarily* dispensed” means. “When unclear questions are included in a survey, they may threaten the validity of the survey by systematically distorting responses if respondents are misled in a particular direction, or by inflating random error if respondents guess because they do not understand the question.” Reference Manual on Scientific Evidence (2d ed. 2000), at 248.

Finally, Plaintiff admits that there may have been an “oversight” in allowing the survey responses to include data for DES prescribed for all ailments, not just to prevent accidents of pregnancy. Plaintiff’s Opposition at 11. There is no evidence as to what percentage of DES prescriptions were for ailments other than accidents of pregnancy. Thus, Mr. Sparr’s survey cannot reliably say anything about the market share that is relevant to this case - the DES market (brand specified or not) in 1969 and 1970 in Allston, Massachusetts prescribed for accidents of pregnancy.

E. PLAINTIFF’S COUNSEL’S AFFIDAVIT DOES NOT CURE THE FLAWS IN MR. SPARR’S PROFFERED TESTIMONY

Plaintiff’s counsel’s affidavit fails to cure the deficiencies in Mr. Sparr’s expertise or in the methodology of his “market survey.” To the contrary, Mr. Levine confirms Lilly’s point that “[f]requently, identification evidence points to non-Lilly defendants.” Affidavit of Aaron M. Levine, Esquire Regarding Identification, dated July 5, 2006, at ¶13. While Mr. Levine denies

involvement in Mr. Sparr's work with Dr. Vanderschmidt aside from the initial discussion over survey criteria, he does not deny that the goal of the survey was to identify Lilly as the prevalent DES manufacturer, nor does he deny that he directed Mr. Sparr to search for and interview pharmacists with the specific goal of identifying Lilly. *See, e.g.*, Sparr Tr. at 57 (Dwyer Aff., Exh. 1) ("Q. Did you understand when you were interviewing those pharmacists that the goal was to see if the pharmacist would remember Eli Lilly and Company as the drug that they had? A. Yes."); Letter from Harold Sparr to George Friedman, R.Ph., dated December 5, 2003 (Dwyer Aff., Exh. 6) ("The current lawsuits involve the Liability Insurance Company who insured Eli Lilly & Co.").

Mr. Levine also acknowledges in his affidavit that often the identification evidence is so deficient that DES cases are dismissed or rejected outright, such as "if the mother of the plaintiff... cannot remember what pill she took, and if there are no pharmacy records or live pharmacists." Here, Plaintiff's mother cannot remember the manufacturer or any other identifying details of the pill she took. For the reasons discussed in Lilly's Memorandum In Support Of Its Motion For Summary Judgment, her description of a white, cross-scored pill does not sustain Plaintiff's burden of identifying Lilly. There also are no pharmacy records or live pharmacists from the relevant pharmacy. Accordingly, Mr. Levine's affidavit confirms that this case is no different from the others that could not survive summary judgment.

F. MR. SPARR'S TESTIMONY DOES NOT SUSTAIN PLAINTIFF'S BURDEN ON SUMMARY JUDGMENT.

Plaintiff's suggestion that Mr. Sparr's testimony is confirmed by Lilly's purported "silence" with respect to evidence of a non-Lilly DES product "somewhere in the pipeline" is nonsensical. It is Plaintiff's burden to sustain her burden of proof on the issue of product identification, and yet she concedes that Mr. Sparr's testimony is not, by itself, sufficient to meet

this burden. Plf. Opp. at 1. Further, there is no dispute that there were dozens of other DES manufacturers during the relevant time period, yet Mr. Sparr professes to have experience only with Lilly. Indeed, Plaintiff sued a number of other DES manufacturers in this lawsuit.

CONCLUSION

For the foregoing reasons, Lilly respectfully requests that the Court strike Mr. Sparr's statement from the record. Lilly submits that Mr. Sparr's statement is incompetent for lack of personal knowledge, unreliable, and will not assist the Court in understanding the evidence relevant to this case, thus warranting its exclusion pursuant to Federal Rules of Evidence 602 and 702.

REQUEST FOR HEARING

Pursuant to LCvR 7(f), Lilly requests a hearing on its Motion to Strike the Statement of Harold Sparr.

Respectfully submitted,

ELI LILLY AND COMPANY

By its attorneys,

/s/ James J. Dillon

James J. Dillon (BBO # 124660)

Brian L. Henninger (BBO # 657926)

Foley Hoag LLP

155 Seaport Boulevard

World Trade Center West

Boston, MA 02110-2600

(617) 832-1000

Dated September 5, 2006